HEW NEWS

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FOR RELEASE AT 12 NOON
June 23, 1976

Guidelines for the conduct of experiments involving recombinant DNA molecules were released today by Dr. Donald S. Fredrickson, Director of the National Institutes of Health.

Dr. Fredrickson also released a document describing the factors he took into account in reaching his decision to issue the Guidelines.

The NIH Guidelines will, effective today, govern research at laboratories of the NIH and those of its grantees and contractors. They are also expected to be adopted by other laboratories throughout the United States and foreign countries.

The NIH has also undertaken an environmental impact assessment of these Guidelines for recombinant DNA research in accordance with the National Environmental Policy Act of 1969 (NEPA). The purpose of this assessment is to review the environmental effects, if any, of research that may be conducted under the Guidelines.

Recombinant DNA molecules result from recombination in the test-tube of segments of deoxyribonucleic acid, the material which determines the hereditary characteristics of all living cells. These techniques have a remarkable potential for furthering the understanding of fundamental biochemical processes in cells of lower and higher organisms, and promise to revolutionize molecular

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biology. But the technology, which permits genetic information from very different organisms to be combined, also involves potential hazards which are difficult to evaluate. Therefore the research must proceed with considerable caution.

Medical advances to be expected through the use of this technology include the opportunity to explore the functioning of cells in complicated diseases. Understanding of a variety of hereditary defects may be significantly enhanced, and some may be able to be prevented or modified. In the future it may be possible to use this technology to produce in microorganisms medically important compounds for the treatment and control of disease.

There are risks in the new research as well as potential benefits. Microorganisms with transplanted genes--called "chimeras"--may prove hazardous to human or other forms of life. Thus special provisions are necessary for their containment.

The NIH Guidelines establish carefully controlled conditions for the conduct of experiments involving the production of such molecules and their insertion into organisms such as bacteria. These Guidelines replace the recommendations contained in the 1975 Summary Statement of the Asilomar Conference on Recombinant DNA Molecules. The latter would have permitted research under less strict conditions than the NIH Guidelines.

The chronology leading to the present Guidelines is described in detail in the NIH Director's decision document. In summary, scientists engaged in this research called, in 1974, for a moratorium on certain kinds of experiments until an international meeting could be convened to consider the potential hazards of recombinant DNA molecules. They also called upon the NIH to establish a committee to provide advice on recombinant DNA technology.

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The international meeting was held at the Asilomar Conference Center, Pacific Grove, California, in February 1975. The consensus of this meeting was that certain experiments should not be done at the present time, but that most of the work on construction of recombinant DNA molecules should proceed with appropriate physical and biological barriers. The Asilomar Conference report also made interim assignments of the potential risks associated with different types of experiments. The NIH then assumed responsibility for translating the broadly based Asilomar recommendations into detailed guidelines for research.

Dr. Fredrickson reached his decision on the Guidelines after extensive scientific and public airing of the issues during the sixteen months which have elapsed since the Asilomar Conference. The issues were discussed at public meetings of the Recombinant DNA Molecule Program Advisory Committee (Recombinant Advisory Committee) and the Advisory Committee to the NIH Director. The Recombinant Advisory Committee extensively debated three different versions of the Guidelines during this period.

The Advisory Committee to the NIH Director, augmented with consultants representing law, ethics, consumer affairs and the environment, was asked to advise as to whether the proposed Guidelines balanced responsibility to protect the public with the potential benefits through the pursuit of new knowledge. The many different points of view expressed at this meeting were taken into consideration by the Director in making his decision. Dr. Fredrickson emphasized, however, that NIH will continue to consider issues raised by the scientific community and the public on this type of research.

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The NIH Guidelines identify experiments which are not to be performed at the present time. For permissible experiments, the Guidelines define different levels of physical and biological containment, and classify containment criteria for different kinds of recombinant DNAs. Used in the combination specified in the Guidelines, these measures are designed to afford protection to workers and the environment while permitting this important line of research to proceed.

The NIH Guidelines also define the responsibilities of investigators, institutions where the research is conducted, and NIH staff and advisory committees.

Dr. Fredrickson noted that NIH recognizes a special obligation to disseminate the Guidelines as widely as possible. Accordingly, the Guidelines will be sent to all of the approximately 25,000 NIH grantees and contractors. Major professional societies which represent scientists working in this area will also be asked to endorse the Guidelines.

The Guidelines will be sent to medical and scientific journals. Dr. Fredrickson will ask the editors of these journals to request that investigators include a description of the physical and biological containment procedures used in any recombinant research they report on.

Dr. William Gartland, who will head the NIH Office of Recombinant DNA Activities, will leave today for Geneva to brief various international health and scientific organizations with responsibility in this area. He will meet with the World Health Organization Advisory Committee on Medical Research that will be reviewing this matter this week.

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Dr. Gartland will also brief appropriate officials at the European Molecular Biology Organization and in Great Britain. The Guidelines have also been sent to all science attaches of foreign embassies located in Washington and to U. S. science attaches in our embassies in foreign countries.

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